DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
9 2032d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

December 7, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Osamu Irie, President
Osamu Corporation
15002 S. Avalon Ave.
Gardena, CA 90248

WL-09-02

Dear Mr. Irie:

We inspected your manufacturing facility, located at 15002 S. Avalon Ave., Gardena, CA 90248 on September 14, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your seafood products, including cooked, ready-to-eat salmon flakes; cooked, ready-to-eat eel; and raw tuna to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for "cooked and chilled seafood" does not list the critical control point of labeling for controlling the food safety hazard of *Clostridium botulinum* that may occur in vacuum packaged products after they are thawed if they are temperature abused. FDA recommends that frozen vacuum packaged products be labeled, "Important, keep frozen until used, thaw under refrigeration immediately before use."

2. You must list critical limits that are sufficient to control the food safety hazard, to comply with 21 CFR 123.6(c)(3). However, your HACCP plan for "cooked & chilled seafood" has an insufficient critical limit [redacted] to control pathogen survival through cooking, in that no time parameter is listed. Your time/temperature critical limits to control pathogen survival must be set through scientific means; that is, you must document that the critical limits that you have chosen to control the hazard will be effective.

3. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, our investigator observed that you did not measure the internal temperature of the fish you were processing.

4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor protection of food

contact surfaces and cross contamination with sufficient frequency to ensure control, as evidenced by:

a) The hand dip station is not maintained. No hand sanitizer was observed in the receptacle located at the hand sanitizing station. No employees handling cooked ready-to-eat products were observed using any hand sanitizer during production.
b) A broken light shield was observed over a fluorescent light in the production area.
c) Aprons were observed stored in close proximity to exposed in-process product.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a new/revised HACCP plan and associated forms, e.g. monitoring forms or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your written reply should be addressed to:

Thomas L. Sawyer, Director, Compliance Branch
U. S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

If you have questions regarding any issue in this letter, please contact Robert B. McNab, Compliance Officer at (949) 798-7709.

Sincerely,

4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor protection of food